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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,273	08/27/2001	Gust H. Bardy	032580.0027.UTL	5279
21691	7590	10/17/2005		
CROMPTON SEAGER AND TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER MULLEN, KRISTEN DROESCH	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No. 09/940,273	Applicant(s) BARDY ET AL	
	Examiner Kristen Mullen	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/2/05, 7/13/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-219 is/are pending in the application.
 4a) Of the above claim(s) 1-52 and 137-219 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 95-125 and 127-136 is/are allowed.
- 6) ☒ Claim(s) 53, 54, 61, 63, 70, 71, 76, 77, 84-86, 88-90 and 126 is/are rejected.
- 7) ☒ Claim(s) 55-60, 62, 64-69, 72-75, 78-83, 87 and 91-94 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/11/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: ACTIVE HOUSING AND SUBCUTANEOUS ELECTRODE CARDIOVERSION/DEFIBRILLATION SYSTEM.

2. The specification contains references to parent applications by their application numbers. Some or all of these applications have since been issued. The examiner respectfully requests that the parent application information be updated in the specification along with any other referenced application numbers in the specification that have matured into patents.
3. The specification contains references to commonly owned patent applications without application numbers but identified by title. The examiner respectfully requests that this information be updated with the corresponding application numbers.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 84-86, 88-90 and 126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 84 and 126 each recite the limitation "the anterior portion of a patient's ribcage" spanning lines 2-3.

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Claims 85, 86, 88 and 89 each recite the limitation "the patient" in the last line of the respective claims.

Claim 90 recites the limitations "the third rib" in line 3, "the twelfth rib" in line 4, and "the patient" in line 6.

There is insufficient antecedent basis for these limitations in these claims.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 53, 54, 61, 63 and 76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 79 and 99 of U.S. Patent No. 6,647,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

8. Claims 53, 61, 63, 70-71 and 77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 25, 42, 82, 84, 95, 105, 113, 114 and 117 of U.S. Patent No. 6,721,597. Although the conflicting claims are not

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identical, they are not patentably distinct from each other because the claims of the present application are broader and are met by the narrower patent claims (the patent claims contain all the limitations of the present application claims).

Response to Arguments

9. The rejections based on Hauser (5,385,574) have been withdrawn.

Allowable Subject Matter

10. Claims 95-125 and 127-136 are allowed.

11. Claims 55-60, 62, 64-69, 72-75, 78-83, 87 and 91- 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claim 53-54, 61, 63, 70-71 and 76-77 would be allowable if rewritten or amended to overcome the Double Patenting rejection(s) set forth in this Office action.

13. Claim 84-86, 88-90 and 126 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: Applicant's have submitted a declaration by a cardiologist under 37 C.F.R. 1.132. In that declaration, the declarant has stated that in the context of cardioversion-defibrillation treatment of a patient, an electrode, lead, or lead system that resides at least in part within a patient's vasculature or at least in part within a patient's heart is identified as a transvenous electrode, lead, or lead system and would not identify such electrode, lead, or lead system that resides at least in part within a patient's vasculature or at least in part within a patient's heart as subcutaneous.

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While Hauser (5,385,574) shows two subcutaneous electrodes that are also located on opposite ends of the housing, it does not teach that cardioversion-defibrillation is delivered between the two subcutaneous electrodes.

Causey III (5,411,547, cited in IDS) and Dahl et al. (5,230,337, cited in IDS) each show two epicardial or subcutaneous electrodes and the delivery of cardioversion-defibrillation Between the two subcutaneous electrodes. However, Causey does not teach the housing or canister acts as one of the subcutaneous electrodes. Dahl does not teach the housing or canister acts as one of the subcutaneous electrodes and shows the housing located in the abdominal area.

Anderson et al. (5,376,103, cited in IDS) and Adams (5,601,607, cited in 892) show two subcutaneous electrodes, one located on the housing and one located on a lead. Like Hauser, these references do not teach that cardioversion-defibrillation is delivered between the two subcutaneous electrodes

KenKnight (6,148,230, cited in 892) also shows at two subcutaneous electrodes, including the housing. Like the above discussed references, it does not teach that cardioversion-defibrillation is delivered between two subcutaneous electrodes.

15. The functional language “wherein a cardioversion-defibrillation energy is delivered between the first and second subcutaneous electrodes” recited in each of the independent claims has been considered as critical to establishing novelty of the claimed invention. The examiner is hesitant to assert that the delivery of cardioversion-defibrillation between first and second subcutaneous electrodes (as defined by the applicants) is an inherent feature of the structures of the prior art. See *In re Schreiber*, 128 F.3d 1473, 1477-78, (Fed. Cir., 1997); and *In re Swinehart*, 439 F.2d 210, 212-13 (C.C.P.A., 1971).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kristen Mullen
Patent Examiner
Art Unit 3766

kdm

Kristen Mullen